Cancer Clinical Trials Advisory Council

Causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials

Updated: October 19, 2011

The following comments were gleaned from council discussion and may not represent the consensus or even the majority opinion of the Council members. It is a working list to which the Council may react, revise, or recommend additions and deletions. All parties on the Council seemed to acknowledge that a problem exists and that the problem can be resolved with additional effort.

- Providers may not understand the differences between fully-insured and self-insured plans, causing the incorrect impression that the insurance company has a policy of exclusion or denial rather than a responsibility to faithfully execute the terms of the employee plans which they administer. Providers might screen candidates from trials based on this incorrect impression.

- Employers and insurers may believe trials add unacceptable cost to care. They may not understand that according to recent studies, clinical trials do not add cost to routine patient care, thus unnecessarily denying payment for routine care when it would not have added costs. The cancer treatment itself is expensive. The trial sponsor covers the additional cost of experimental elements. The only increase in cost for routine care accompanied by a trial protocol occurs if the patient lives longer than otherwise.

- Trials may require patients to go out of state. This would add to costs.

- Insurers and employers may not understand that Oncology is not like other specialties. Clinical trials ARE the standard of care. Oncologists are trained in and expected to use clinical trial with patients as often as appropriate.

- Employers providing self-funded coverage may believe that clinical trials are always experimental in nature and exclude them from their plan coverage categorically.

- Employers providing self-funded coverage may be concerned about stop loss coverage denial if their self-funded plans begin to cover routine care in clinical trials.

- It creates an uneven playing field for insurers to provide coverage in their fully-insured products for individuals and small groups, if ERISA-regulated self-funded plans for large groups are not held to the same standard.

- The problem is hard to document because few clinics or insurers track information about denials or exclusions, and those who do, do not distinguish between fully-insured and

self-insured plans. The Insurance Commissioner does not require reporting on this measure.

- It is a frightening time for health insurance companies with compounding costs and new regulations. It's difficult to assume (what appears to be) additional costs until it is required.

- Contracts are written to prevent abuses. The language needed to prevent abuses may serve to screen out candidates that are indeed appropriate for coverage.

- Coverage decisions are not predictable. Some patients with unusual persistence, energy and support are better able to negotiate with their insurers or employers. Patients with less energy are more likely to give up and less likely to get the results they want. This adds to inconsistent and inequitable experience among patients and greater confusion and frustration.

- Consistent opportunity by insurers to review trial protocols may lead to more approvals. A more cooperative process for review might allow for some up-front agreements that could speed approval and treatment.

- Failure to reach agreement in 2007 when many states had done so, took the wind out of the sails. Factors today may provide new wind. There may be more agreement to use common guidelines from NCCN (National Comprehensive Cancer Network)

- Insurers and employers may not understand the differences between trials in various phases. This may cause them not to consider coverage of trials in certain phases

- Disagreement comes when it is not clear who will be covering the administration of the clinical trial.

- Denials may be the result of concern over who will cover the cost of adverse events resulting from the clinical trial.

- Some providers may engage in their own "off label trial" after reading about promising results in the literature. In these situations, insurers maybe accused of denial when the care is not part of an approved trial.